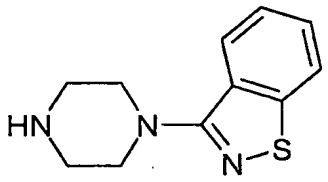
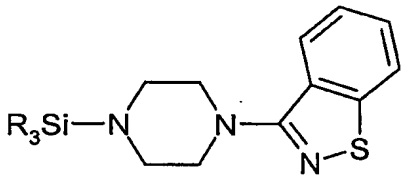
We claim:

1. A process for preparing 5-[2-[4-(1,2-Benzisothiazol-3-yl)-1-piperazinyl] ethyl]-6-chloro-1,3-dihydro-2H-indol-2-one (ziprasidone) of formula I:
or a pharmaceutically acceptable salt thereof; or a solvate or a hydrate thereof.;
which comprises;
a) silylating 1-(1,2-benzisothiazol-3-yl)piperazine of formula II:



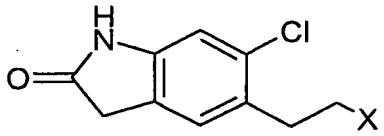
---------- II

with a silylating agent to form compound of formula III:



---------- III

where in R is independently alkyl;
b) reacting the silyl compound of formula III with 5-(2-haloethyl)-6-chloro-oxindole compound of formula IV:



---------- IV

wherein X is fluoro, chloro, bromo or iodo;
in a solvent in the presence of a base to neutralize hydrohalic acid, at 40°C to reflux temperature of the solvent used to form the compound of formula I and optionally converting the compound of formula I into a pharmaceutically acceptable acid addition salt thereof; or a solvate or a hydrate thereof.

2. The process according to claim 1, where in silylation step(a) is carried out with a silylating agent in the presence of a solvent and a tertiary amine base.

3. The process according to claim 2, wherein the silylating agent is selected from trialkylsilyl halides, N,O-bis(trimethylsilyl)-acetamide and N,N'-bis(trimethylsilyl)-urea.

4. The process according to claim 3, wherein the silylating agent is selected from trialkylsilyl halides.

5. The process according to claim 4, wherein the silylating agent is a trialkyl silyl chloride.

6. The process according to claim 3, wherein the silylating agent is selected from trimethylsilyl chloride, triethylsilyl chloride, N,O-bis(trimethylsilyl)-acetamide and N,N'-bis(trimethylsilyl)-urea.

7. The process according to claim 6, wherein the silylating agent is trimethylsilyl chloride.

8. The process according to claim 1, wherein solvent used in silylating step(a) is selected from ethyl acetate, methyl acetate, isopropyl acetate, tert-butyl methyl acetate, ethyl formate, acetonitrile, dimethylsulfoxide, dioxane, cyclohexane, n-hexane, benzene, toluene, xylene, methylene chloride, chloroform, carbontetrachloride, ethylene dichloride, acetone, methyl ethyl ketone, methyl isobutyl ketone, diethyl ketone, tert-butyl methyl ether, diethyl ether, diethyl carbonate, and a mixture thereof.

9. The process according to claim 8, wherein the solvent is selected from methylene chloride, ethylacetate, cyclohexane, ethylene dichloride and a mixture thereof.

10. The process according to claim 9, wherein the solvent is methylene chloride.

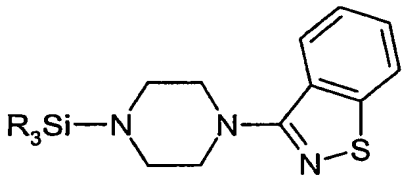
11. The process according to claim 1, wherein X of the compound of formula IV is chloro, bromo or fluoro.

12. The process according to claim 11, where in X is chloro.

13. The process according to claims 1, 11 and 12 wherein the solvent used in step(b) is selected from ethyl acetate, methyl acetate, isopropyl acetate, tert-butyl methyl acetate, ethyl formate, methanol, ethanol and isopropyl

alcohol, acetonitrile, tetrahydrofuran, dimethylformamide, dimethyl sulfoxide, dioxane, cyclohexane, n-hexane, benzene, toluene, xylene, methylene chloride, chloroform, carbontetrachloride, ethylene dichloride, acetone, methyl ethyl ketone, methyl isovutyl ketone, diethyl ketone, tert-butyl methyl ether, diethyl ether, diethyl carbonate, water and a mixture thereof.

14. The process according to claim 13, wherein the solvent is selected from dimethylformamide, methylisobutylketone, water or a mixture thereof.
15. The process according to claim 1, wherein base used to neutralize hydrochloric acid is selected from alkaline metal carbonates, alkalinemetal bicarbonates, anhydrous ammonia, aqueous ammonia, pyridine, hydrides and tertiary amines.
16. The process according to claim 15, wherein the base is selected from sodium carbonate, potassium carbonate, sodium bicarbonate, potassium bicarbonate, triethylamine and diisopropylethylamine.
17. The process according claim 16, wherein the base is sodium carbonate or potassium carbonate.
18. The process according to preceding claims wherein the reaction is carried out at 50^{0}C to reflux temperature of the solvent used.
19. The process according to claim 18, wherein the reaction is carried out at 80^{0}C to reflux temperature of the solvent used.
20. The process according to claim 19, wherein the reaction is carried out at reflux temperature of the solvent used.
21. The process according to claim 17, wherein the base is sodium carbonate.
22. The compounds of formula III:



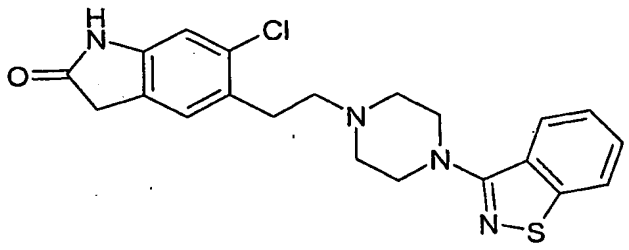
---------- III

wherein R_3 groups are independently alkyl.

23. The compound of claim 22, wherein R groups are independently methyl or ethyl.

24. The compounds of claim 23, wherein R groups are all methyl or all ethyl.

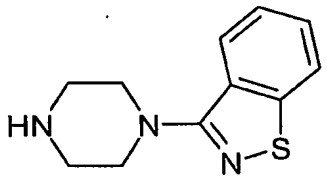
25. A process for preparing ziprasidone for formula I



---------- I

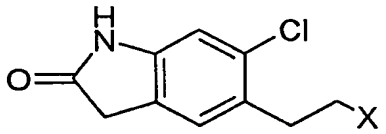
or a pharmaceutically acceptable salt thereof; or a solvate or a hydrate thereof;

which process comprises reacting 1-(1,2-benzisothiazol-3-yl)piperazine of formula II:



---------- II

with 5-(2-haloethyl)-6-chloro-oxindole of formula IV:



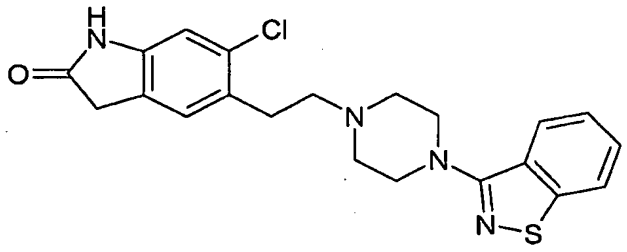
---------- IV

wherein X is fluoro, chloro, bromo or iodo;

in the presence of liquor ammonia and an alkaline metal carbonate, alkaline metal bicarbonate to form ziprasidone of formula I; and optionally converting ziprasidone formed into a pharmaceutically acceptable acid addition salts of ziprasidone; or a solvate or a hydrate thereof.

26. The process according to claim 25, wherein X of formula IV is chloro, bromo or iodo.

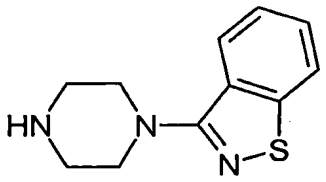
27. The process according to claim 26, wherein X is Cl.
28. A process according to claim 1, further comprises controlling the mean particle size of ziprasidone, pharmaceutically acceptable acid addition salts of ziprasidone; and solvates and hydrates thereof formed in step (b) by a method of compacting using compacting machine.
29. The process according to claim 28, the said pharmaceutically acceptable acid addition salt is ziprasidone hydrochloride and the said hydrate is ziprasidone hydrochloride hemihydrate or ziprasidone hydrochloride monohydrate.
30. The process according to claim 29, the mean particle size of the said product is about 80 microns or above
31. A process for preparing ziprasidone of formula I



---------- I

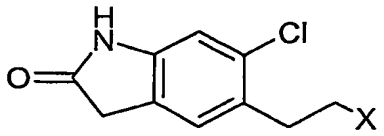
or a pharmaceutically acceptable salt thereof; or a solvate or a hydrate thereof;

which process comprises reacting 1-(1,2-benzisothiazol-3-yl)piperazine of formula II:



---------- II

with 5-(2-haloethyl)-6-chloro-oxindole of formula IV:



---------- IV

wherein X is fluoro, chloro, bromo or iodo;

in the presence of pyridine and aqueous monomethylamine to form ziprasidone of formula I and optionally converting ziprasidone formed into a pharmaceutically acceptable acid addition salts of ziprasidone; or a solvate or a hydrate thereof.

32. The process according to claim 31, wherein X of formula IV is chloro, bromo or iodo.

33. The process according to claim 32, wherein X is chloro or bromo.

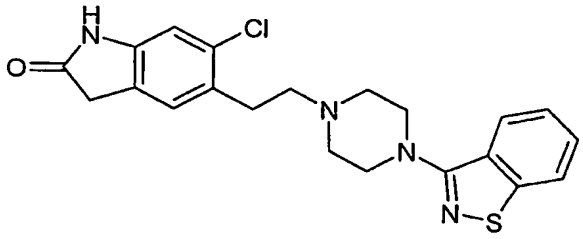
34. The process according to claim 33, wherein X is chloro.

35. The process according to claim 31, wherein pharmaceutically acceptable salt is ziprasidone hydrochloride.

36. The process according to claim 31, wherein the hydrate is ziprasidone hydrochloride hemihydrate.

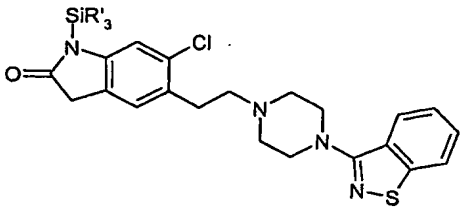
37. A process for purification of ziprasidone free base or a pharmaceutically acceptable acid addition salts of ziprasidone; or a solvate or a hydrate, the said process comprises:

i) silylating crude ziprasidone of formula I:



---------- I

with a silylating agent to form silyl compound of formula V:



------- V

wherein R' groups are independently alkyl, and

ii) deblocking the silyl protecting group of the compound of formula V formed in step (i) to precipitate ziprasidone of formula I as ziprasidone free base or a pharmaceutically acceptable acid addition salt; or a solvate or a hydrate thereof, as crystalline salt.

38. The process according to claim 37, wherein silylating agent is selected from trialkylsilyl halides, N,O-bis(trimethylsilyl)-acetamide and N,N'-bis(trimethylsilyl)-urea.

39. The process according to claim 38, wherein trialkylsilyl halide is trialkylsilyl chloride.

40. The process according to claim 38, wherein the silylating agent is selected from trimethylsilyl chloride, triethylsilyl chloride, N,O-bis(trimethylsilyl)-acetamide and N,N-bis(trimethylsilyl)-urea.

41. The process according to claim 40, wherein the silylating agent is trimethyl silyl chloride.

42. The process according to claim 37, wherein the solvent used in silylation step is selected from ethyl acetate, methyl acetate, isopropyl acetate, tert-butyl methyl acetate, ethyl formate, acetonitrile, dimethylsulfoxide, dioxane, benzene, toluene, xylene, methylene chloride, chloroform, carbontetrachloride, ethylene dichloride, acetone, methyl ethyl ketone, methyl isobutyl ketone, diethyl ketone, tert-butyl methyl ether, diethyl ether, diethyl carbonate and a mixture thereof.

43. The process according to claim 42, wherein the solvent used is selected from methylene chloride, ethylacetate, cyclohexane, ethylene dichloride, toluene, carbon tetrachloride and a mixture thereof.

44. The process according to claim 43, wherein the solvent is selected from methylene chloride, ethyl acetate, cyclohexane, ethylene dichloride and a mixture thereof.

45. The process according to claim 37, wherein the silylation is carried out in the presence of a tertiary amine base.

46. The process according to claim 45, wherein the base is triethylamine, N,N-dimethyl-4-aminopyridine or trimethylamine.

47. The process according to claim 37, wherein the deblocking step(ii) is carried out by contacting the silyl compound of formula V with a protic solvent, water or an acid for sufficient time to effect deblocking.

48. The process according to claim 47, wherein the protic solvent is an alcohol, and the acid is selected from hydrochloric acid, hydrobromic acid, hydroiodic acid and methanesulfonic acid.

49. The process according to claim 48, wherein the alcohol is ethanol or methanol.

50. The process according to claim 48, wherein the acid is hydrochloric acid.

51. The process according to claim 50, wherein ziprasidone is isolated as ziprasidone hydrochloride; or hydrates thereof.

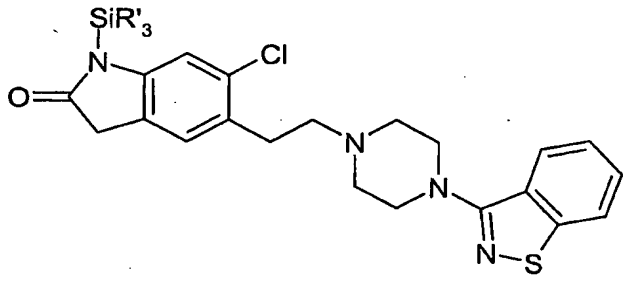
52. The process according to claim 51, wherein hydrates of ziprasidone hydrochloride is ziprasidone hydrochloride hemihydrate or ziprasidone hydrochloride monohydrate.

53. The process according to claim 52, wherein hydrate of ziprasidone hydrochloride is ziprasidone hydrochloride hemihydrate.

54. The process according to claim 48, wherein the protic solvent is methanol.

55. The process according to claim 47, wherein the solvent is water.

56. Compounds of formula V:



---------- V

wherein R^1 groups are independently alkyl.

57. The compounds as defined in claim 56, wherein R^1 groups are Independently methyl or ethyl.

58. The compounds as defined in claim 57, wherein R^1 groups are all methyl or all ethyl.